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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,677	11/07/2002	Muhammed Majeed		9298

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EXAMINER

ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/065,677

Applicant(s)

MAJEED ET AL.

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/7/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Claim Objections

1. Claims 3-7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim because each of these claims depends in a non-alternative way on more than one claim. See MPEP § 608.01(n).
2. Claim 1 is objected to because of the following informalities: The word "a" should be inserted in front of the first occurrence of the word "methanol" on line 5. Appropriate correction is required.
3. Claim 9 is objected to because of the following informalities: The space between "hydro" and "chloride" on line 2 should be removed. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "an amine such as triethylamine" in lines 5-6. The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Claim 1 and its dependents are therefore rendered indefinite.

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5. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-11 lack terminating periods and therefore do not define proper claims. Claims 1-11 are therefore rendered indefinite.
6. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 5 recite broad temperature ranges followed by narrow temperature ranges. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 4 recites the broad recitation 0° to 60°C, and the claim also recites 0° to +10°C and 20° to +40°C which are the narrower statements of the range/limitation. Claim 5 recites the broad recitation 0° to 50°C,

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and the claim also recites 30° to +40°C which is the narrower statement of the range/limitation. Claims 4 and 5 are therefore rendered indefinite.

7. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 5 recite the limitation "the solvent" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 6 and 7 are therefore rendered indefinite.
8. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "an aromatic aldehyde such as benzaldehyde" in lines 5-6. The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Claim 8 is therefore rendered indefinite.
9. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 is drawn to the racemization of D- or L-methylselenocysteine by use of an aromatic aldehyde, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claim 8 is therefore rendered indefinite.

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10. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites two different definitions for the variable group R in lines 4-5 and 6. It is unclear which of these definitions is to be applied to the variable group R. The scope of claim 9 is unascertainable and it is therefore rendered indefinite.
11. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 is drawn to a process for the manufacture of chloroalanine methyl ester by use of thionyl chloride, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claim 11 is therefore rendered indefinite.
12. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 recites the limitation "chloroalanine methyl ester" for the product of the reaction but employs the L-serine methyl ester hydrochloride as the starting material. It is unclear what the stereochemistry of the product is (D, L, racemic or other mixture). Claim 11 is therefore rendered indefinite because the product is incompletely defined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by

Andreadou et al (Journal of Medicinal Chemistry, Synthesis of Novel Se-Substituted Selenocysteine Derivatives as Potential Kidney Selective Prodrugs of Biologically Active Selenol Compounds: Evaluation of Kinetics of β -Elimination Reactions in Rat Renal Cytosol, 1996, 39(10), pages 2040-2046). Andreadou discloses (Page 2044, column 1, 7th paragraph and page 2041, column 2, top, Scheme 2) the synthesis of Se phenyl-Lselenocysteine via the reaction of sodium phenyl selenide and β -chloroalanine. Andreadou further discloses the formation of sodium phenyl selenide via the reduction of diphenyl diselenide using sodium borohydride at 0°C. Claims 9 and 10 are therefore anticipated by Andreadou.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walsh et al

(The Journal of Biological Chemistry, Studies on the Mechanism of D-Amino Oxidase, 1971, 246(22), pages 6855-6866) in view of Patai (The Chemistry of the Carbon-Halogen Bond, Part 1, 1973, John Wiley & Sons, New York, pages 463-466).

Instantly claimed is a process for producing chloroalanine methyl ester hydrochloride from L-serine methyl ester using thionyl chloride (SOCl_2). NOTE: For the purposes of this rejection the Examiner assumes that the claimed process involves contacting L-serine methyl ester with thionyl chloride.

Walsh teaches (Page 6857, column 1, lines 13-29) a method for the synthesis of DL- β -chloroalanine methyl ester hydrochloride that comprises contacting DL-serine methyl ester with PCl_5 to produce DL- β -chloroalanine methyl ester hydrochloride after precipitation with solvent.

The difference between the instantly claimed process and that taught by Walsh is that Walsh employs PCl_5 as the chlorinating agent while the use of SOCl_2 is instantly claimed. Walsh does not suggest this modification.

Patai, however, teaches (Page 464, line 24, equation (39) and page 463, lines 26-33 including equation (37)) the art-recognized functional equivalence of SOCl_2 and PCl_5 as reagents for the conversion of alcohols to the corresponding chlorides by replacement of the hydroxyl group. Patai further teaches (Compare equations (37) and (39)) that the other product of reaction of an alcohol with SOCl_2 is the gas SO_2 .

One of ordinary skill in the art would therefore have been motivated by the teaching of Patai to replace the PCl_5 employed in the process of Walsh with the functionally equivalent SOCl_2 which produces only gaseous by-products. This substitution simplifies product recovery, reduces waste disposal requirements and therefore reduces the overall cost of the process. There would have been a reasonable expectation for success based upon Patai's teaching of the functional equivalence PCl_5 and SOCl_2 for the desired transformation.

Thus the instantly claimed process would have been obvious to one of ordinary skill in the art.

Conclusion

15. Claims 1-11 are pending. Claims 1-11 are rejected.

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

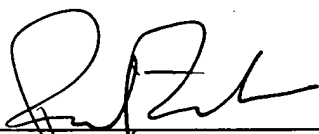
- a. Grummon et al (US 3,678,067 07-1972): Teaches a process for the formation of seleno-derivatives of amino acids but does not teach or suggest the use of an amine in the isolation of the product.
- b. Chibata et al (US 4,401,820 08-1983): Teaches a process for the racmization of optically active amino acids using an aromatic aldehyde and aliphatic acid but does not teach or suggest the use of the process for selenium-containing amino acids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read 'Paul A. Zucker', is written over a horizontal line.

Paul A. Zucker, Ph.D.
Patent Examiner
Technology Center 1600